



## **Economic Impact Analysis Virginia Department of Planning and Budget**

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**22 VAC 30 - 40 – Protection of Participants in Human Research**  
**Department of Rehabilitative Services**  
March 17, 2008

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### **Summary of the Proposed Amendments to Regulation**

These regulations provide a basis for the Department of Rehabilitative Services (Department) to oversee human subjects research involving the Department, the Woodrow Wilson Rehabilitation Center, sheltered workshops, and independent living centers (covered entities). The Department proposes to make several changes to these regulations to reflect federal law. The new language reflects the federal requirements that have been implemented in Virginia since 2005. Additionally, the Department proposes to establish a specified deadline of 45 days after the end of each state fiscal year for covered entities to send a written report to the Department, add clarifying language, and revise definitions. The proposed regulations also preclude covered entities from establishing their own human research review committee (HRRC) or to affiliate with other covered entities to establish a central HRRC in lieu of using the Department's HRRC.

### **Result of Analysis**

The benefits likely exceed the costs for all proposed changes.

### **Estimated Economic Impact**

Other than clarifications and definitional language that does not affect requirements, most of the proposed amendments to these regulations reflect changes to federal law that have been applied in Virginia since 2005. These proposed amendments will thus have no impact on requirements, but may produce a small benefit through clarification of the rules to the public.

The current regulations permit covered entities to use their own or a joint HRRC in lieu of the Department's HRRC. According to the Department, no covered entity has ever done so,

nor has any indicated an intention to do so in the future. Thus, the proposal to preclude covered entities from establishing their own HRRC should have no impact.

The Department also proposes to require that

No later than 45 days after the end of each state fiscal year, Woodrow Wilson Rehabilitation Center, sheltered workshops and independent living centers shall send a written report to the commissioner giving assurance that either all human subjects research conducted during the fiscal year was reviewed and approved by the department's HRRC prior to implementation of that research or that no human subjects research was conducted during that state fiscal year.

Currently the covered entities are required to send such reports, but no deadline is specified. According to the Department all covered entities have in practice complied with sending their reports within 45 days after the end of each state fiscal year when prompted. Thus, this proposal will not practically create a new cost for covered entities, but will produce a small benefit by clarifying to institutions when the Department actually needs the reports and may result in less time spent by Department staff contacting covered entities.

## **Businesses and Entities Affected**

These regulations potentially affect the Woodrow Wilson Rehabilitation Center, the 71 private sheltered workshops in Virginia, the 16 independent living centers in the Commonwealth, and the clients and staff at these covered entities.<sup>1</sup>

## **Localities Particularly Affected**

The proposed regulations affect localities throughout the Commonwealth.

## **Projected Impact on Employment**

The proposed amendments will not significantly affect employment.

## **Effects on the Use and Value of Private Property**

The proposed amended language will not significantly affect the use and value of private property.

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<sup>1</sup> Data Source: Virginia Department of Rehabilitative Services

## **Small Businesses: Costs and Other Effects**

The proposed amended language will not significantly affect small businesses.

## **Small Businesses: Alternative Method that Minimizes Adverse Impact**

The proposed amended language will not significantly affect small businesses.

## **Real Estate Development Costs**

The proposed amended language will not affect real estate development costs.

## **Legal Mandate**

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with Section 2.2-4007.04 of the Administrative Process Act and Executive Order Number 36 (06). Section 2.2-4007.04 requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has adverse effect on small businesses, Section 2.2-4007.04 requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.